

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERGE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,000	11/25/2003	Peter L. Collins	2303-18-14	6530
7590 08/07/2006		EXAMINER		
GRAYBEAL JACKSON HALEY LLP			LUCAS, ZACHARIAH	
Suite 350 155-108th Avenue NE			ART UNIT	PAPER NUMBER
Bellevue, WA 98004-5901			1648	

DATE MAILED: 08/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

	-	Application No.	Applicant(s)
Office Action Summary		10/722,000	COLLINS ET AL.
		Examiner	Art Unit
		Zachariah Lucas	1648
Period fo	The MAILING DATE of this communication app	pears on the cover sheet with the c	orrespondence address
A SHOWHIC - Exter after - If NO - Failu Any r	ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DO ISSUE IN THE MAILING THE MAIL	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be timwill apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE	I. nely filed the mailing date of this communication. D (35 U.S.C. § 133).
Status			
2a)□	Responsive to communication(s) filed on <u>25 N</u> . This action is FINAL . 2b) This Since this application is in condition for allowar closed in accordance with the practice under E	action is non-final.	
Dispositi	on of Claims		
5)□ 6)□ 7)□ 8)⊠ Applicati 9)□ 10)□	Claim(s) 1-65 is/are pending in the application. 4a) Of the above claim(s) is/are withdray. Claim(s) is/are allowed. Claim(s) is/are rejected. Claim(s) is/are objected to. Claim(s) 1-65 are subject to restriction and/or expension on Papers The specification is objected to by the Examine. The drawing(s) filed on is/are: a) accomplicant may not request that any objection to the Replacement drawing sheet(s) including the correct. The oath or declaration is objected to by the Examine.	wn from consideration. election requirement. er. epted or b) objected to by the Edrawing(s) be held in abeyance. See ion is required if the drawing(s) is obj	e37 CFR 1.85(a). ected to. See 37 CFR 1.121(d).
	nder 35 U.S.C. § 119	armier. Note the attached office	Action of 101111 1 10-102.
12)[/ a)[Acknowledgment is made of a claim for foreign All b) Some * c) None of: Certified copies of the priority documents Certified copies of the priority documents Copies of the certified copies of the priority documents application from the International Bureau ee the attached detailed Office action for a list	s have been received. s have been received in Application it is a property of the contraction of the contraction is a property of the contraction	on No d in this National Stage
2) Notice 3) Inform	e of References Cited (PTO-892) of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal Pa 6) Other:	

Application/Control Number: 10/722,000 Page 2

Art Unit: 1648

DETAILED ACTION

1. Claims 1-65 are pending in the application.

Priority

2. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The application does not include a reference, including the application number, the relationship of the present application to, and the filing date, of parent application 09/291,894. In order for Applicant to receive benefit to this prior application, to other applications through the claim to this application, the specification must be amended to include the required reference.

Because the claim to priority to this prior application was recognized in the filing receipt, the Applicant is not required to submit a Petition for Unintentionally Delayed Claim for Priority in order to gain benefit of the prior application.

Election/Restrictions

- 3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-36, 46-63, drawn to isolated chimeric RSV, classified in class 435, subclass 235.1.

Application/Control Number: 10/722,000 Page 3

Art Unit: 1648

II. Claims 37-45, drawn to methods for stimulating an immune response against RSV comprising the administration of a chimeric RSV, classified in class 424, subclass 211.1.

III. Claims 64 and 65, drawn to methods for the production of an infectious chimeric RSV virus, classified in class 435, subclass 69.1.

The inventions are distinct, each from the other because of the following reasons:

- 4. The inventions of Groups III and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the claimed product may be made through use of the method of Group III, or through alternative methods such as using cells and a helper virus. The product is therefore distinct from the claimed method for the production thereof.
- 5. The inventions of Groups I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the claimed product may be used in alternative methods, such as for use as a vector for the expression of non-RSV proteins, or in methods for the detection of RSV antibodies in diagnostic assays. The product is therefore distinct from the claimed method.

Application/Control Number: 10/722,000 Page 4

Art Unit: 1648

6. The inventions of Groups II and III are directed to related methods. The related

inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually

exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are

either not capable of use together or can have a materially different design, mode of operation,

function, or effect. See MPEP § 806.05(j). In the instant case, the claimed methods are drawn to

a method of producing, and a method of using, a product. The methods are therefore mutually

exclusive in scope, and have materially different modes of operation and functions. The methods

are therefore distinct one from the other.

Species Election

7. This application contains claims directed to the following patentably distinct species:

For Group I above: the Applicant is required to elect

One of the RSV from which the heterologous sequence is to be derived from those listed

in claim 3

One of the proteins to be modified (listed in claim 4) and if one of the F, G, or SH

proteins is elected, to one of the regions thereof identified in claim 5

One of the functions of the modifications from those identified in claim 22 as well as the

gene to be modified from those listed in claim 24

One of the further modifications selected from:

the 4 additional modifications identified in claim 30

Art Unit: 1648

II.

the additional modification of claim 31, and if the additional modification to claim 31 is elected to one of the regions, one of the proteins, and one of the source PIVs identified in claim 33.

the inclusion of a second heterologous sequence as indicated in claim 11, or the inclusion of an additional mutation as indicated in claim 12, and if the additional mutation of claim 12 is elected, to one of or a combination of the mutations identified in claims 13-15.

For Group II above, election is required to one of the target populations identified in claim 41.

8. The species are independent or distinct. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the various species are drawn to virus comprising different mutations of combinations of mutations. They therefore represent mutually exclusive embodiments that have materially different designs. They are therefore distinct.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic for Group I, and claim 37 is generic for Group

Art Unit: 1648

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Conclusion

- 9. Because these inventions are distinct for the reasons given above, different classifications, and because the literature and sequence searches required for any one of the groups is not required for the others, restriction for examination purposes as indicated is proper.
- 10. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to

Application/Control Number: 10/722,000 Page 7

Art Unit: 1648

retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

- 11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
- 12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 10/722,000

Art Unit: 1648

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Page 8

Z. Lucas

Patent Examiner